MINUTES OF THE PHARMACEUTICAL MANAGEMENT AGENCY (PHARMAC)

BOARD MEETING DECEMBER 2021

The meeting was held at Pharmac offices, Level 9, 40 Mercer Street, Wellington and by videoconference starting at 9.30am with the following attendees:

Board members

Steve Maharey Jan White	
Ross Lawrenson	
Nicole Anderson	
Claudia Wyss	
Elizabeth Zhu	
Mark Weatherall	
Jane Thomas	
Lisa Lawrence	
Anthony Jordan	
Talia Anderson-Town	

Chair Deputy Chair Board Member Board Member Institute of Directors, Future Director Observer, PTAC Chair Observer, new PTAC Chair Observer, new Board member Observer, new Board member

Pharmac staff in attendance

Sarah Fitt Lizzy Cohen Lisa Williams Peter Alsop Michael Johnson Mark Woodard Kathryn McInteer David Hughes Trevor Simpson Chief Executive Board Secretary Director of Operations Director of Engagement & Implementation Director of Strategic Initiatives Director of Corporate Services/CFO Incoming Director Finance and Corporate Chief Medical Officer Chief Advisor Māori

Jannel Fisher, Caroline De Luca, Josh Wiles, Emma Clarke, Rochelle West, Andrew Davies, Mark Brewer, Davina Carpenter and Chloe Dimock (Pharmac staff) attended for relevant items. Some attendees joined via videoconference to present papers.

The Board meeting started with Pharmac's kaumatua, Bill Kaua, joining to lead a mihi whakatau/welcome to new Board members Talia Anderson-Town and Dr Anthony Jordan and a poroporoaki/farewell departing Board members Ross Lawrenson and Nicole Anderson.

1. Directors' Only Discussion

- 1.1 Glossary of Terms
- 1.2 Board Actions

The Board noted the Board Actions.

1.3 Board Annual Agenda 2021

The Board noted the Board Annual Agenda 2021.

1.4 Board Annual Agenda 2022

The Board noted the Annual Agenda 2022.

2. Apologies

Peter Bramley, Observer, DHB Representative.

3. Record of Previous Board and Committee Meetings

3.1 Minutes of October 2021 Board Meeting

resolved to adopt the minutes of the October 2021 meeting as being a true and correct record.

Nicole Anderson and Jan White

(carried)

3.2 Minutes of October 2021 Health and Safety Committee meeting

noted the minutes from the October 2021 Board Health and Safety Committee meeting

endorsed the Committee's 2022 work programme

noted that work has commenced to implement the recommendations from the Independent review of the Health and Safety framework

noted the Board discussion at the November Board meeting regarding COVID-19 vaccination of Pharmac staff.

3.3 Audit and Risk Committee Recommendations

A verbal update was provided by the Committee Chair on the 3 December 2021 Committee meeting. The Board:

resolved to recommend to the Board that the Board Chair and the Audit and Risk Committee Chair sign the letter of representation

resolved to recommend to the Board that the Board Chair and the Audit and Risk Committee Chair sign the Statement of Responsibility in the Annual Report

noted the Committee discussion on risk will be covered under the Board risk Report item

noted that the Committee discussed the progress of staff to implement the recommendations from the external audit

agreed to recommend to the Board the appointment of a new Committee Chair

resolved to appoint Talia Anderson-Town as the Chair of the Audit and Risk Committee

noted that the Board will discuss the Committee's membership at the January 2022 Board meeting, noting that, in addition to Nicole Anderson's term, Committee member and Board member Ross Lawrenson's term has expired and the need to appoint another member to the Committee. Steve Maharey and Claudia Wyss (carried)

3.4 Summary of August 2021 PTAC advice and recommendations

This paper informs the Board of recommendations made and advice given by Pharmacology and Therapeutics Advisory Committee (PTAC) at its August 2021 meeting held on 19 and 20 August 2021 via videoconference. The Board:

noted the following summary of the record of the PTAC meeting held on 19 and 20 August 2021 via videoconference

noted the August 2021 PTAC record was signed off by the Chair on 3 November 2021 and is published on the Pharmac website

noted the verbal update from the PTAC Chair to provide further detail on the summary of PTAC recommendations in the Board report

noted the difficulty with external communications where PTAC have made high priority recommendations to Pharmac, when there are limited CPB funds available for new investments. The Board suggested that staff add links to the funding decision process within the website location for PTAC records to ensure context is available for the public reading the PTAC records. The Board discussed the need for staff to better highlight an assessment of the impact for Māori and other disadvantaged groups for each medicine considered by PTAC (as part of the Factors for Consideration (the 'Factors')., The Board recommended that staff include Māori impact statements in the PTAC records for each medicine and that staff may like to consider structuring the PTAC records using the Factors as a framework

noted that the Consumer Advisory Committee members attended the November PTAC meeting, instead of the August meeting as previously communicated to the Board.

4. Interests Register

noted the interests register

noted any decisions by the Chair to manage actual or potential conflicts of interest, as follows:

[None required]

noted that the interest register will be updated to reflect the new Board member's interests for January 2022 Board meeting and that, for the new members who were observing, no potential conflicts of interest have been identified for this meeting. With new members present at this Board meeting, the Chair summarised the process of recording interests and potential conflicts before board meetings.

5. Matters Arising

noted the matters arising and actions progressed.

noted that the Board will complete a capability assessment in the new year which will inform training opportunities for the Board (collective Board and individual members)

as part of the Board's te Tiriti accountabilities. This will be reflected on the Board actions report and the 2022 Board Annual Agenda.

6. Chair's Report

6.1 Verbal Report

A verbal update was provided by the Board Chair. The Board:

noted new COVID-19 Omicron variant

noted that the Chair, Chief Executive and new Board member Dr Anthony Jordan are participating in various groups to support implementation of the health reforms

noted that the Chair and Chief Executive met with Ministry of Health staff as part of a regular six monthly meeting on Pharmac performance and strategic matters

noted that the Chair and Chief Executive have met with the new Board members as part of their induction to the Pharmac Board

noted that the Chair and Chief Executive appeared before the Petitions Committee on 11 November 2021 regarding the Petition of Richard Edward Stein: Fund ustekinumab for New Zealanders with severe Crohn's and ulcerative colitis

noted that the Chair and Chief Executive met with Medicines NZ as part of the regular six monthly meeting

noted that the Chief Executive has responded to the External Review Committee Chair's letter regarding the redaction of information provided to the Review Committee.

6.2 Correspondence

noted the correspondence report.

7. CE Report

7.1 Chief Executive's Report

noted the Chief Executive's Report

noted that since this report was written, the Pharmac Review Interim Report has been released publicly on 2 December 2021

noted that, at the previous meeting between the Review Committee and the Board, the Review Committee suggested a meeting with the Board in early 2022 and that this is likely to occur on the day of the January 2022 Board meeting. The Board requested that staff coordinate with the Review Secretariate and Chair on agenda items for this meeting

noted that staff are preparing a submission on the Pae Ora (Healthy Futures) bill. One of the issues staff wish to respond to is that the Bill has exempted Pharmac from some health system principles (Clause 7(4) of the draft Bill) which relate to engaging with Māori on developing services, and opportunities for including Māori in decisionmaking (not services, because Pharmac does not provide services). The Board noted

that Pharmac staff were not aware this was going to be included before the Bill was published and shared staff's concern that Pharmac stakeholders may perceive it was intentionally driven by Pharmac. A copy of the submission will be shared with the Board. A Board member also noted that other Boards are providing submissions on the Bill highlighting a change to the wording in the bill, currently worded as 'might' or 'could' engage with Māori, and that Pharmac staff may like to consider including this in our submission

noted the operational finances and the advice from staff that the forecasted loss greater than budget is manageable.

7.2 Monthly Communications Report

The purpose of this paper was to summarise the communications activity for September. The Board:

noted that all five of our proactive media activities in October had media pick up

noted that 60% of our website content has been updated since the launch of the new website and our readability score for content has improved and that the general theme is people are finding what they want

noted that staff have identified four areas we want to focus on next year to improve our reputation score – proactive media, social media partnerships, engagement and transparency

noted that staff are focusing on proactive communications and looking wider than traditional channels, such as Women's Weekly article

noted the benefit of using an influencer for the 'You are a Priority' campaign and that this has informed a change in our social media approach, to use other people's social media platform. Staff commented that this is an approach that other government agencies are using and that we are careful to select influencers that are aligned with our organisational values and link to our work

discussed the media coverage on the release of the Pharmac Review Interim Report and supported staff to continue with their communications approach and activities.

8. Key Items

8.1 Annual Report 2020/21

This paper sought Board approval and signing of the Annual Report for 2020/21. The Board:

noted the Chair of the Audit and Risk Committee provided a verbal briefing to the Board regarding discussions earlier in the day with staff from Audit NZ, which included:

- a summary of discussions with Audit NZ staff and the contents of Audit NZ's final report
- a recommendation to progress matters related to the annual report

noted we have made changes to the Annual Report to accommodate feedback from the Board and Audit NZ

approved the Pharmac Annual Report for 2020/21

agreed that the Board Chair and the Audit and Risk Committee Chair sign the Annual Report, Statement of Responsibility and the Letter of Representation for the year ended 30 June 2021

The Board congratulated staff on preparing a document which is easy to read and that could support further proactive communications on some aspects of our work highlighted in the report.

Jan White and Nicole Anderson

(carried)

8.2 Budget bids for Budget 2022

This paper set out Pharmac's proposed Budget 2022 bid for the Combined Pharmaceutical Budget (CPB) bid as well as budget bids that we shall be seeking for COVID-19 related activity.

9. Schedule and Funding

9.1 Budget Management Update

This paper updates the Board on the Pharmaceutical Budget, including November 2021 CPB Forecast and COVID-19 related expenditure. It aims to enable a wider discussion by the Board regarding management's planned activities to manage expenditure in 2021/22 and in the out-years. It also provides an update on COVID-19 costs being incurred and any associated risks.

9.2 Pharmaceutical Transactions Report

The Board:

noted the update from Pharmac staff on current issues and the large and/or significant medicines transactions that are currently planned or in progress.

9.3 Proposal to secure supply of Pfizer's oral protease inhibitor for the treatment of COVID-19

This proposal is to enter the Binding Term Sheet ('the Agreement') with Pfizer to secure supply of its oral protease inhibitor for the treatment of COVID-19 in New Zealand. Having regard to the decision-making framework set out in Pharmac's Operating Policies and Procedures, the Board:

resolved to approve the Binding Term Sheet with Pfizer New Zealand Limited (Pfizer) to secure supply of protease inhibitor PF-07321332 + ritonavir (hereinafter for ease of understanding, referred to by its proposed brand name, Paxlovid) for the treatment of New Zealand patients with mild to moderate COVID-19

noted that the Binding Term Sheet would commit Pharmac to the purchase of 60,000 treatment courses of Paxlovid and would be conditional upon Medsafe approval

noted that following approval of this proposal by the Pharmac Board of Directors the Chief Executive would sign the Binding Term Sheet on behalf of Pharmac

noted that the costs associated with this decision would be met from available COVID-19 funds and that this decision is another example of Pharmac making use of the COVID-19 fund to fund COVID-19 treatments

noted that the government have determined that Pharmac will be the lead purchasing agent for COVID-19 treatments

noted that clinical advice has not yet been sought regarding Paxlovid, however due to global demand, an expedited decision to secure stock is required

noted that clinical advice will be sought regarding Paxlovid, from Pharmac's COVID-19 Treatments Advisory Group in December 2021

noted if secured and approved by Medsafe, supply of Paxlovid could be available to New Zealand patients from quarter two 2022

noted that public consultation on this proposal was not possible prior to making any decision due to the urgency required to secure supply for New Zealand; however, Pharmac would retain the option to consult on the eligibility criteria for Paxlovid at a later date, if this was required

noted that the target population for treatment with Paxlovid, and eligibility criteria are yet to be proposed. This paper seeks approval of an advance purchase agreement only. Any proposal relating to eligibility criteria would be subject to a separate decision paper and would likely involve targeted consultation with the health sector

noted the difficulty in administering this treatment in the community due to the timing of infection and start of treatment, however acknowledged that this is one treatment in a portfolio of treatments which will provide options, which is particularly important if there are issues with supply of other treatments or there is a change in efficacy of treatments etc

noted that there is some risk to Pharmac's reputation that people may think that Pharmac is investing in COVID-19 treatments instead of investing in other new medicines. The Board considered that careful communications to explain this unusual situation would be required to mitigate this risk.

Claudia Wyss and Jan White

(carried)

9.4 Proposal to secure additional supply of casirivimab and imdevimab for the treatment of COVID-19

The proposal is to amend the Advance Purchase Agreement with Roche to secure additional supply of casirivimab and imdevimab (Ronapreve) for the treatment of patients with COVID-19 in New Zealand for the 2022 calendar year. Having regard to the decision-making framework set out in Pharmac's Operating Policies and Procedures, the Board:

resolved to approve the updated Advanced Purchase Agreement with Roche Products (New Zealand) Limited (Roche) to secure additional supply of casirivimab and imdevimab for the 2022 calendar year for the treatment of New Zealand patients with mild to moderate COVID-19

noted that the updated Advanced Purchase Agreement would commit Pharmac to the purchase of an additional 7,500 doses of casirivimab and imdevimab and would remain conditional upon Medsafe approval

noted that this proposal follows the decision by the Pharmac Board in October 2021 to secure supply of an initial order of 5,300 doses of casirivimab and imdevimab

noted that this proposal follows communication from Roche that the global cut-off for 2022 orders of casirivimab and imdevimab is 1 December 2021

noted that the costs associated with this decision would be met from available COVID-19 funds

noted that clinical advice has been sought from Pharmac's recently established COVID-19 Treatments Advisory Group to ensure the treatment is targeted to the patients most likely to benefit

noted it is expected casirivimab and imdevimab will be available in New Zealand from early 2022

noted that public consultation on this proposal has not been undertaken due to the short timeframes for securing supply; however, Pharmac retains the option to consult on the proposed eligibility criteria for casirivimab and imdevimab once they have been finalised

Nicole Anderson and Claudia Wyss

(carried)

9.5 Named Patient Pharmaceutical Assessment Update

This paper provides the Board with an annual update on Pharmac's management of applications under the Exceptional Circumstances framework for 2020/21 and to highlight any particular areas where there have been changes in outcomes or approach since the last report. The Board:

noted the Named Patient Pharmaceutical Assessment (NPPA) activities since the previous update to the Board in October 2020

noted Pharmac received 1,393 NPPA applications during 2020/21. This is 66 applications more than 2019/20 and continues the upward application trend since 2017/18

noted the NPPA assessment pathway remains important for patients with rare disorders and/or exceptionally high and unusual health needs to access funding for treatments. Examples of some important treatments that have been funded under the NPPA Policy in 2020/21 are outlined

noted the Exceptional Circumstances Framework also provides a mechanism for Pharmac to make decisions about funding treatment for specific patients outside of the Pharmaceutical Schedule and separate to the NPPA Policy. Examples of these in 2020/21 are outlined

noted following positive feedback from pharmacists and clinicians in 2019/20, Pharmac plans to update NPPA related data available on our <u>website</u> with a further 18 months of application outcome data.

noted that staff are planning to conduct a business process review, internal and external, on the exceptions applications process to identify improvements and to make it less burdensome for clinicians so that it is not a barrier for patients access to treatments. Staff indicated input would be sought from clinicians that submit NPPA applications. A Board member suggested staff also seek input from applicants. Staff noted that currently they actively encourage applicants to phone us for assistance so the process is not more complicated than it needs to be

noted that regular reviews of external facing policies are desirable and that staff will identify a review date for the NPPA policy.

9.6 Medical Devices and Transaction Investment Report

This paper provided the Board with a monthly update on progress with medical devices national contracting activity. The Board:

noted the update on progress with medical devices national contracting activity and work towards the Statement of Performance Expectations target

noted that since the Board paper was prepared, staff have secure contracts that cover \$456 million of annual DHB hospital expenditure on medical devices, so good progress to our target

noted that staff have increased engagement with the Health Transition Unit on a procurement and supply chain framework

noted the findings in the UK that pulse oximeters have been found to be less effective on darker coloured skin. Staff noted that assessing suitability of medical devices for gender and race is relevant in our work to fund medical devices

noted that FPIM is being rolled out in Taranaki

noted that the additional freight costs due to COVID-19 supply disruptions has been lower than expected.

9.7 Summary of decisions made under delegated Authority – October 2021

This report contained a summary of all decisions made by Pharmac staff under delegated authority since the last Board meeting. The Board:

noted the summary of decisions made under Delegated Authority during October 2021 by the Chief Executive, Director of Operations, Manager Pharmaceutical Funding, Senior Advisor/Team Leader and Senior Therapeutic Group Managers/Team Leaders

noted the membership of the COVID-19 Treatments Advisory Group and that staff are progressing with appointing a consumer representative.

Chief Executive left the meeting.

10. Strategic Planning and Policy

10.1 Progress on the continuous improvement of Pharmac's medicine assessment and funding decision-making processes

This paper provided the Board with an update on progress with the end-to-end review of our medicines assessment and decision-making process project. The Board:

noted that current work to improve transparency and timeliness of medicine funding applications is a continuation of efforts initiated in 2018 to make Pharmac's processes faster, clearer, and simpler

noted that as part of the Enhance Key Functions strategic priority, an end-to-end analysis project was commissioned in February this year and we have recently completed one of our significant project objectives

noted the broad findings of the end-to-end process analysis, and the process improvement work programme that has subsequently been initiated

noted that the Interim Report of the external review of Pharmac identified timeliness, public transparency, and the accessibility of Pharmac's decision making processes as key themes

noted that the Board will receive another update on the end-to-end analysis project in March 2022

noted the great work of staff to progress with process improvement activities which is crucial for delivering better outcomes for New Zealanders and acknowledge that it was unfortunate this work was not recognised in the Interim Review Report

noted that staff have been very engaged with the process improvement work, to the point where demand might outstrip ability to make change

noted that in 2022 staff intend to engage with the Ropu, CAC and PTAC on staff's 'Blue Skies' project.

10.2 Increasing New Zealand business access to Pharmac procurement opportunities

This paper outlined our approach to increasing opportunities for Māori, Pacific and New Zealand-owned businesses to engage with Pharmac procurement opportunities. The paper also summarised contracts awarded in the first quarter of this financial year that we are required to report to TPK and MBIE. The Board:

noted that a progressive procurement policy to increase the diversity of government suppliers and achieve broader economic and social outcomes has been approved by Cabinet

noted there is a special focus to increase the proportion of relevant contracts awarded to Māori businesses across mandated government agencies, which includes Pharmac

noted that the Government has set a target to award Māori businesses five percent of all annual procurement contracts, and we are required to report to Te Puni Kōkiri

(TPK) and the Ministry of Business, Innovation & Employment (MBIE) on this in their capacity as lead government agencies in the progressive procurement initiative

noted that TPK and MBIE have advised that the panel of consultancy services has increased its diversity of government suppliers so there will be a lot more Māori businesses which we will have access to, to help us to reach the target. A Board member noted that there are more panels opening up so we are hopeful that we will see more diversity of suppliers over the next couple of years

noted that the Government has decided that pharmaceutical (medicines, medical devices and related products) procurement is exempt from this target. Despite this, our aim is to reduce barriers for engagement and support improving the competitiveness of Māori and other New Zealand businesses in our pharmaceutical procurement activities

noted that for Pharmac's operational (non-pharmaceutical) procurement, reaching the Government set target will require a considered and planned approach

noted the activities Pharmac staff are progressing to consider initiatives to become a customer of choice for Māori businesses

noted that staff are also working together as an organisation to increase Māori providers and find businesses to engage with us. Staff are also looking at our procurement process to identify opportunities to make it less cumbersome on suppliers

noted that it is pleasing to see Pharmac staff looking at this.

11. Regular Reports and Noting Papers

11.1 Risk Report - Exceptions

The full risk register was considered by the Audit and Risk Committee and provided to the Board as an information item. The register lists risks that exceed the Board's identified risk tolerance. This paper is an exception report for the Board about changes to the register. The Board:

noted the summary risk report, which provided an update on items on the Board risk register that have materially changed since the quarter one risk register was reviewed by the Board in October 2021

noted that the Audit and Risk Committee reviewed the November updated risk register when it met on 3 December 2021

12. Interest Articles

noted the interest articles.

13. General Business

The Board said farewell to Board members, Ross Lawrenson and Nicole Anderson, Mark Woodard, Director of Corporate/CFO, Lizzy Cohen, Board Secretary, and Mark Weatherall, PTAC Chair.

Date of Next Meeting

The date for the next Board meeting is set for Friday 28 January 2022.

The meeting closed at 2.30pm with a karakia.

Chair:

Date: